



June 28, 2024

DePuy Ireland UC
% Kathy Boggs
Regulatory Affairs Project Leader
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46582

Re: K232303

Trade/Device Name: ATTUNE® Porous Fixed Bearing Tibial Base with AFFIXIUM™ 3DP Technology; ATTUNE® Porous Medialized Dome Patella with AFFIXIUM™ 3DP Technology; ATTUNE® Porous Medialized Anatomic Patella with AFFIXIUM™ 3DP Technology

Regulation Number: 21 CFR 888.3565

Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis

Regulatory Class: Class II

Product Code: MBH, JWH

Dear Kathy Boggs:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on December 11, 2023. Specifically, FDA is updating this SE Letter because FDA inadvertently indicated that the SE determination also included review and clearance of a predetermined change control plan (PCCP). However, your 510(k) submission did not include a PCCP, so FDA is providing this administrative correction. Please see the attached revised clearance letter.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Lixin Liu, OHT6: Office of Orthopedic Devices, 301-796-3480, Lixin.Liu@fda.hhs.gov.

Sincerely,

Lixin Liu -S

Lixin Liu, Ph.D.

Assistant Director

DHT6A: Division of Joint Arthroplasty Devices

OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health



June 28, 2024

DePuy Ireland UC
% Kathy Boggs
Project Leader Regulatory Affairs
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46582

Re: K232303/S001

Trade/Device Name: ATTUNE® Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM™ 3DP Technology

Regulation Number: 21 CFR 888.3565

Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis

Regulatory Class: Class II

Product Code: MBH, JWH

Dated: August 1, 2023

Received: August 1, 2023

Dear Kathy Boggs:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on December 11, 2023.

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lixin Liu-S

Lixin Liu, Ph.D.

Assistant Director

DHT6A: Division of Joint Arthroplasty Devices

OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K232303

Device Name

ATTUNE® Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM™ 3DP Technology

Indications for Use (Describe)

The ATTUNE Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM 3DP Technology are intended for cementless use within the ATTUNE® Total Knee Replacement System. Porous coated implants may be used with or without cement.

Candidates for total knee replacement include patients with a severely painful and/or impaired knee function resulting from osteoarthritis, post-traumatic arthritis, or a failed previous implant (provided that adequate bone is present).

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

(As required by 21 CFR 807.92 and 21 CFR 807.93)

Contact Details	
Applicant Name	DePuy Ireland UC
Applicant Address	Loughbeg, Ringaskiddy Co. Cork Munster, IRELAND
Applicant Contact Telephone	574-404-8711
Applicant Contact	Kathy Boggs
Applicant Contact Email	Kboggs2@its.jnj.com
Correspondent Name	DePuy Orthopaedics, Inc.
Correspondent Address	700 Orthopaedic Drive Warsaw IN 46582 United States
Correspondent Contact Telephone	574-404-8711
Correspondent Contact	Kathy Boggs
Correspondent Contact Email	Kboggs2@its.jnj.com
Date prepared	December 11, 2023
Device Name	
Device Trade Name	ATTUNE® Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM™ 3DP Technology
Common Name	Total Knee Prosthesis
Classification Name	Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulation Number	21 CFR 888.3565; 21 CFR 888.3560
Product Code(s)	Primary: MBH Secondary: JWH
Regulatory Class	Class II

Legally Marketed Predicate Devices	
K202194	ATTUNE® Porous Fixed Bearing Tibial Base, Medialized Dome Patella, and Medialized Anatomic Patella with AFFIXIUM™ 3DP Technology
Legally Marketed Reference Devices	
K132624	Stryker Triathlon Tritanium Metal-Backed Patella
Device Description Summary	
The ATTUNE® Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM™ 3DP Technology are compatible with the ATTUNE Knee System composed of individually packaged femoral, tibial and patellar components designed to replace the natural articular surface of the knee joint. The femoral component is a metal implant with or without porous coating. The tibial component may be comprised of a metal tibial base with or without porous coating, and a polyethylene insert and locking components, or be an all polyethylene device. The patella component may be of an all polyethylene design or a polyethylene patella with porous metal backing.	
Intended Use/Indications for Use	
The ATTUNE Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM 3DP Technology are intended for cementless use within the ATTUNE® Total Knee Replacement System. Porous coated implants may be used with or without cement. Candidates for total knee replacement include patients with a severely painful and/or impaired knee function resulting from osteoarthritis, post-traumatic arthritis, or a failed previous implant (provided that adequate bone is present).	
Indications for use Comparison	
The indications for use are the same as the predicate device.	
Technological Comparison	
The DePuy ATTUNE Porous Fixed Bearing (FB) Tibial Base, Medialized Dome Patella, and Medialized Anatomic Patella with AFFIXIUM 3DP Technology are similar to the predicate DePuy ATTUNE Porous Fixed Bearing (FB) Tibial Base, Medialized Dome Patella, and Medialized Anatomic Patella with AFFIXIUM 3DP Technology (K202194) in principle of operation, intended use, classification, design, materials, and fixation. The ATTUNE Porous FB Tibial Base with AFFIXIUM 3DP Technology is manufactured from Titanium alloy (Ti-6Al-4V), available in sizes 1-10, and intended for cementless or cemented use within the ATTUNE Total Knee Replacement System. The bone apposing surfaces are comprised of 3D printed fixation features with a porous and solid geometry that enable biological fixation of the implant to the bone. The proximal surface is designed to work with currently available ATTUNE FB tibial inserts. The ATTUNE Porous Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM 3DP Technology are manufactured from 3D printed Titanium alloy (Ti-6Al-4V) substrate for the bone opposing surfaces with the articulation surface being produced from AOX ultra high molecular weight polyethylene (UHMWPE). The patellae are available in sizes 32, 35, 38, and 41mm and are intended for cementless or cemented use within the ATTUNE Total Knee Replacement System. The articular surface is designed to work with currently available ATTUNE Femoral Components.	

Non-Clinical and/or Clinical Tests Summary & Conclusions

The following tests were performed (per FDA's Class II Special Controls Guidance Document: Knee Joint Patellofemoral and Femoral Tibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA) to demonstrate substantial equivalence of safety and efficacy with the predicate devices:

- Peg Fatigue Testing for ATTUNE Cementless Patella
- Stryker Peg Fatigue Benchmark Testing for ATTUNE Cementless Patella
- Biocompatibility Evaluation Report (Patella)
- MRI Testing (Tibial Base & Patella)

Clinical testing was not required to demonstrate substantial equivalence.

The subject DePuy ATTUNE Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM 3DP Technology are substantially equivalent to the predicate device DePuy ATTUNE Porous Fixed Bearing Tibial Base, Medialized Dome Patella and Medialized Anatomic Patella with AFFIXIUM 3DP Technology (K202194).